REMARKS

Status of Claims

Claims 1 - 5 are present for examination. and in the Examiner's paper mailed 05/17/06, the Examiner has rejected Claims 1 - 5 under Simpson, et al U 2002/0090725 and Burgess et al, US 6,559. 119 in the Examiner's office action.

On 09/14/06, applicants presented a six page explanation of the claims and a rebuttal to the rejection. However, the explanation comprised six pages of single spaced typing. Those remarks are reproduced below but are presented with space and a half spacing and with 12 point font to make the remarks more readable when rescanned.

A Notice of Non-Compliance was sent to applicant on 12/06/06 because the response filed on 08/14/06 was not signed. A second Notice of Non-Compliance was mailed on 10/05/06 because of a fee deficiency.

On 01/05/07, after a further review of Simpson and Burgess, cited in the Examiner's action of 05/17/06, applicant mailed in a Suplemental Response that narrowed claim 1 and the that also added new claims 6 – 14. Claims 13 and 14 were independent and were believed to be of sufficiently narrow scope to avoid Simpson and Burgess. However, the added new claims were underlined and the rules say that new claims should not be underlined.

On 04/17/07 the Examiner mailed an Office Communication that requested information relating to the amended claims that would assist the Examiner with his examination. This response has further narrowed Independent claims 13 and 14 and added new dependent claims 15 and 16 that depend from claims 13 and 14 respectively.

In addition, typographical errors such as miss spelled words and improper paragraphing has been corrected in the new claims added originally with applicant's response of 01/05/07

Claim 1 is now amended to make the claim more definite. It should be noted that the mat is produced by electrospinning and offers the advantages, pointed out in the specification, that unlike molded plastic lens material, the invention lens will permit the movement of water between and through the fibers and it is believed that this wicking feature is unique to the claimed invention lens. Existing materials used for contact lens production do not allow for a sufficient passage of oxygen to the surface of the eye. That problem is discussed in the specification. In addition, the use of an alternating source overcomes the problem associated with charge build up on fibers that results in whipping. Solving that problem allows the process to make fiber mats that are optically clear, a feature not taught or required in Simpson where the invention was directed to the process of making scaffold for in vivo applications and structural but not optical use. An optically clear mat is not suggested or taught in Simpson or Burgess. Nanofiber wipping due to charge build up is not of concern in Simpson because of the intended use as a structural in vivo scaffold. The mean diameter of fibers contemplated and made by Simpson are of a diameter that would preclude use in an optically clear mat. The fiber size in the Simpson mats are substantially larger and do not work for the passage of light. I have contacted Wnek, the second principle inventor on the Simpson patent and he informs me that optically clear mats were never contemplated by Simpson nor did the team on the Simpson innovation know how to make an optically clear mat. Dr. Wnek has agreed to provide a declaration to that effect.

There being many points raised by the Examiner in his Communication mailed 04/17/07, each point mentioned by the Examiner in the OA of 04/17/07 will be reviewed and responded to as follows:

"The reply filed on January 5, 2007 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant has amended the claims extensively, yet there is no indication of where the support for many of these amendments occurs."

> **" For instance, paragraphs (c) and (g) added to claim 1 and new claims 13 and 14 do not appear to be supported by the specification as originally filed.**

The steps referenced by the Examiner in Claim 1 with the steps in between are restated below:

c. electrically coupling the target to the power supply first terminal and the needle to the power supply second terminal to permit the power supply to provide and electric field between the target and the needle, and positioning the needle near an electrospinning cone to be formed at a predetermined distance characterized to aid in the electrospinnng process of fiber deposition,

[[a]]d. dissolving a polymer solute in a suitable solvent

[[b]]e. delivering said solute and solvent solution to [[a]] the needle tip

~~c. applying an electric field between said needle and a target~~

[[d]]f. adjusting the output voltage of the power supply to [[increasing]] increase [[an]] the electric field between said needle and target until a Taylor cone is formed, but not of a magnitude to result in a corona discharge or coronal effect,

g. providing a means to vary the source to target distance, and

h. moving the needle in patterns over a region of the target exceeding the perimeter of the contact lens to be formed depositing the eletrospun material as a mat,

The original application is published as US 2005/0067287 on Mar. 31, 2005 and which is equivalent to the original As Filed application, References will be made to that document for support where the paragraph numbering is available if more convenient.

Step c. is supported by 6 and paragraphs 0050 – 0054 which define the reference numbers and terms used in step c. of claim 1. Paragraph 0026 discloses the voltage range of 4000 to 12000 volts and later in the paragraph, the use of alternating the polarity is described as a way to reduce charge build up. The original claim 1, before amendment recited in step d. the phrase "d. increasing an electric field between said

needle and target until a Taylor cone is formed ..." In Paragraph 0026 the phrase "The voltage is adjusted according the distance and desired fiber diameter and structure."

The Examiner refers to step "g." which is now step "h." in claim 1 due to the addition of a paragraph break. Step h. now asks for:

> " h. moving the needle in patterns over a region of the target exceeding the perimeter of the contact lens to be formed depositing the eletrospun material as a mat, ..." .

Step h. finds support for moving the needle in patterns at points in the spec such as at paragraph 0029 where the phrase "moving the cathode target, or vice versa." appears early in the paragraph. A majority of paragraph 0029 is used to describe the steps in patterning the electrospray to create the required mat with fibers having a desired diameter. Also see paragraph 0058 and 0059.

Claims 13 and 14 are new independent claims and it is believed that the above objection and the related support will be applicable.

The Examiner then says "The same for the size of the fibers in new claim 10, some of the materials listed in new claim 11, and the prescriptive surface of claim 12."

Claim 10 contains the phrase "parameters to obtain nanofibers having a diameter in the range of 60-100 nm to mimic the corneal stoma (biomimetic). Claim 10 is now amended to have the phrase "tens of nanometers or less" is present in the spec at paragraph 0029. The limit of 200 nanometers in Claim 6 is supported in paragraph 0026 by the phrase: "

> to enable the construction of a precise electrospun "mat" of polymer material. This electrospun "mat" of polymer fibers could be constructed in such a way as to maintain mean fibril distance of approximately 200 nm (10.sup.-9 meters).

The Examiner's reference to "some of the materials listed in new claim 11," is probably referring to the phrase: "comprises the step dissolving two or more polymers or fiber materials selected from the group comprising collagen, collagen - HEMA, Silicon

hydrogel, Silicon - hydrogel – collagen." The reference to cellulose is deleted. However the reference to HEMA finds support in paragraph 0026 and hydrogel is mentioned in paragraph 0005 and the phrase "a suitable polymer, preferably "Hema", must be created and layered to form the basis of a "mat".

The Examiner's comment regarding claim 12 i.e. "the prescriptive surface of claim 12" is probably referring to the phrase "completed over a region of the target characterized to form a predetermined prescriptive surface on the lens." This claim is directed to the making of a mat for use on a lens having a predetermined optical clarity. At claim 0029 we find the following comment:

> "where a regular matrix of stromal collagen is desired. By rapidly moving the needle in a linear direction for a fixed distance and then reversing such motion with respect to the target, while at the same time indexing the target utilizing a stepper motor drive or piezo stack or other such precision positioner, a series of relatively straight, parallel fibers may be laid down on the target surface. After the desired pattern has been achieved in one axis, the target may be rotated ninety degrees and the process repeated.
>
> Refer to FIG. 6. The outer fringes of a mat matrix so created will be less organized than the central axis as the outer edge is where target position reversal occurs. This area can be trimmed away"

And earlier at paragraph 0005, the specification comments that:

> it is now possible to create a contact lens structure that is made out of varying layers of differing polymer materials, with the possibility of inter-despersement of trapped drug layers to maintain a localized point of contact with the desired drug or medication and the corneal surface.

These statements and others indicate that the claimed process subsumes the steps relating to making material directly to meet specific optical specifications and prescription requirements.

The Examiner next says that

> **"Also, there is no indication that the control of the mean fibril distance as recited in new claim 6 is related to forming a pattern that exceeds the perimeter of the lens.**

The limitation in Claim 6 was discussed above. However, the Examiner appears to believe that the mean fibril distance "is related to forming a pattern that exceeds the perimeter of the lens." The Examiner is correct. There is no relationship between the control of the mean fibril distance is related to the perimeter or diameter of the lens. A given lens might be several thousands of mean fibril distances across. A fibril distance is the distance from one edge of a mat matrix element or grid or triangle. The lens distances is measured in the dimensions relating to the size of a cornea.

The Examiner next comments that:

> **"Instead of showing where support exists, applicant submits that the examiner has used hindsight to reject the claims."**

The remark of this applicant was inappropriate in view of the scope of original claims 1 – 5 and the relevant scope of Simpson, and Burgess.

> **"However, it should be noted that simply adding limitations to claims that are not supported by the original specification is not sufficient to overcome an obviousness rejection. It is also not clear from the response whether applicant believes that the claims as originally presented were obvious but the instant are not.**

The Examiner is thanked for this comment. Some, but not all, of the new claims presented with the response mailed on 09/14/07 although narrowed, may not be

supported by the specification and have been now amended to incorporated limitations believed to be supported by the specification and drawing. The original claims, and the new claims are now believed to be non-obvious and in condition for allowance.

The Examiner then concludes with the remark that:

> **Given that support cannot be found for the instant claims, the response is submitted as being non-responsive to the previous rejection. See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE**

In view of the many changes provoked by Simpson, and the reduced scope of the claims as presently amended, it would be difficult to conclude that the Examiner is totally correct. The term "the instant claims" as used by the Examiner presumably refers to the claims in the 09/14/06 and also those present in the amendments of 01/05//07. Applicant believes that support has been shown to have existed in the specification for most of the claims presented in the amendment mailed on 01/05/06.

Applicant has no knowledge of new matter being added. The claims as now amended and presented are believed to be in condition for allowance and early allowance is requested. If issues exist that the Examiner feels he would like to discuss with the applicant, the Examiner is invited to feel free to call the applicant at his office number below at any time.

Respectfully Submitted,

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